

Digital transformation in the NHS inquiry

PHG
FOUNDATION

making science
work for health

Submitted to

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Social Care Committee

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About the PHG Foundation

1. The PHG Foundation is a non-profit, independent policy think tank and a linked exempt charity of the University of Cambridge. Our mission is making science work for health – providing multi-disciplinary analysis of innovations and ideas in genomics and other biomedical technologies to inform health policy and practice. We have twenty five years' experience in issues surrounding the responsible and effective use of genomics and data in health services, for public health and personalised prevention and treatment.
2. The PHG Foundation is a strong proponent of the potential value of digital technologies, properly used, to improve health and care, and also of the vital importance of harnessing the power of health data for research and future health improvements.
3. Our response to this inquiry draws on a range of recent research projects, reports and other activities that we have undertaken in areas related to this consultation. In particular, our legal and ethical experts have examined a range of relevant issues in the last couple of years, including our reports on the GDPR and genomic data (2020) and Control of patient information in the COVID-19 era (2021) . All our own reports, briefings and other publications are freely available from our website. We would be happy to comment in greater depth or to provide oral evidence.

How can the Government communicate the benefits of digital approaches in healthcare to the public and provide assurances as to the security of their data?

4. Digital transformation is an essential pre-requisite to enabling the effective and efficient use of data generated within the NHS for optimal clinical care, and also for all forms of clinical research including evaluation and quality improvement. From our own research perspective, it is also necessary (though not sufficient) for effective and responsible data sharing within (and in some instances, beyond) the NHS, which enables critical advances in science and medicine.

5. The range of data that is relevant for health research and care has significantly expanded in recent years. Besides routinely collected health data, individual health records may include increasingly complex information from new forms of testing and imaging; digital technologies are essential for capturing, analysing and sharing the insights from such testing. This may also require the digital integration of different types of data, e.g. clinical phenotypic data with genomic sequence data to better understand the role of a particular genetic variant, in causing disease, or digital pathology approaches for automated analysis of digital imaging.
6. In addition, there is increasing scope for the use of digital technologies to generate, record and share information relevant to health outside the traditional confines of the healthcare system, whether through NHS approved digital tools and technologies (including remote monitoring devices and apps) or increasingly though tools that sit outside the formal health system, but which may still offer information relevant to health. We refer to this as citizen generated data; it may include fitness trackers or home monitoring devices, passively generated data through environmental sensors, location data and online activity. Although this does not routinely form part of NHS data assets at present, this is an opportunity that may be embraced in the near future, so digital transformation efforts need to take this into account
7. The inherent challenge in data sharing is that the more informative the data, the greater the risks to privacy posed by sharing that data. Whilst these risks may be mitigated by infrastructural and technological safeguards, residual risks may remain. This is a central practical and cultural challenge to communication and public trust about data security. Moreover, we have found a lack of clarity in the legal frameworks surrounding the use of confidential patient information for genomic and medical research, and confusion among health data custodians and researchers about the appropriate balance between data protection law and the common law of confidentiality.
8. Another complexity is that consent operates differently and has different requirements depending on whether it is consent for the purposes of disclosing confidential information, consent as a legal basis for processing personal data within data protection law, or consent as a requirement of ethical health research. These differences are difficult for professionals to understand, and are highly confusing to individual patients and research participants. A further tension in the genetic/genomic context is that such data are highly identifying and sensitive but that sharing some genetic information can have clear clinical benefits for family members.

9. It is important that clarity across the NHS should be achieved about the proper collection, use and sharing of patient information for clinical care and research – including the limitations and safeguards. Until this is in place, it will significantly hamper effective communication and trust. Generally, front-line health professionals are the public's first port of call for any concerns about privacy. Therefore it is imperative that these same health professionals are clear and confident about the systems and safeguards in place for patient records; the ways in which the information may be used, and by whom; and the benefits and risks this poses. No amount of public information campaigns will effectively counter the problems engendered by health professionals who cannot inform and reassure individuals.
10. However, health professionals are also very busy people who cannot become experts in the complexities of consent, data collection and sharing, regulation and application, including for research; nor do they have time for extended conversations with patients on such issues pertaining to routine data collection. Therefore, there must be clear, simple and readily accessible sources of information made available to all health professionals, alongside consistent and accessible public-facing information.
11. Finally, it is important to note that the single most important step towards assuring the public of the security of their health data is to take proper steps to protect that data – that is, in seeking to engender trust, the system must be appropriately trustworthy. This point was rightly emphasised in the recent Goldacre Review, *Better, Broader, Safer: Using health and care data for research and analysis*. However, whilst there is some scope for legal changes to improve data security, uncertainties will remain, and therefore the most pressing action to ensure consistency, clarity and confidence in how data is collected, used and protected within the NHS is in ensuring that proper guidance is in place.
12. Our recommendation is that the considerable challenges posed by the need to develop, interpret and apply appropriate standards for the protection of privacy, confidentiality and data protection in the health context would be best achieved through the co-development of specific guidance addressing particular topics and issues between regulatory authorities such as the ICO and specialists in health, health data, with strong public involvement at each stage.
13. There is significant potential in the approach recommended in the Goldacre Review, utilising technical measures and re-focusing most secondary research and analysis of patient data within a few trusted research environments (TREs). Transparent and highly secure TREs would address many concerns around the use and dissemination of such data, including privacy and security and increased transparency around who is processing data and for what purposes.

14. However, as the recent experience of the General Practice Data for Planning and Research initiative has emphasised, patient and public confidence is delicate. Communicating benefits and providing assurances is unlikely to assuage all concerns. We believe the time is right for a genuine and broad engagement with the public around the use of health data, in terms of the incredible potential of such data as well as the risks. This is not an easy task. Understanding Patient Data (www.understandingpatientdata.org.uk) have developed a range of resources and examples of good practice that provide a strong starting point but significant resources may be required, especially as this particular resource will not be funded beyond the end of 2022.

What should be the timescale for incorporating genomic data into patients' medical records?

15. Genomic information has considerable potential utility within medicine, most notably to inform cancer diagnosis, prognosis and treatment or more widely, and pharmacogenetic information to inform the choice and dose of selected therapeutics to improve safety and efficacy. In the future, predictive genomic information may offer increasing scope to refine and improve population stratification by risk for preventive measures such as screening and surveillance, and potentially also personalised risk estimates and interventions to improve care. In some cases, genomic information can also be used to identify the presence or risk of rare, inherited diseases in an individual or family, and this sort of information may also have great importance for health and care.
16. However, we would warn against genetic exceptionalism – treating genomic data as uniquely different and distinct from other complex and potentially informative health data. With the notable exception of information about serious, rare heritable forms of disease – which may have implications for family members as well as the relevant individual – genomic data is just an addition to the other forms of information that can inform disease risk prediction, diagnosis and management. Depending on the nature and complexity of the information, and the context in which it is being used, it may require specialised analysis, interpretation and / or patient counselling or communication.
17. In addressing this question, much depends on what is meant by 'genomic data'. Does it refer to the results of tests that employ genomic technologies, or to specific genomic information such as the presence of a specific genetic variant or variants, or to large-scale data such as whole exome or even whole genome sequences? These pose very different challenges.

18. Electronic health records should incorporate information about the results of tests available via the National Genomic Test Directory. For more complex forms of testing, this may need to include expert interpretation of findings from tests. As testing expands, consideration may need to be given to how such information is recorded and shared, but the timescale for such developments should be directed by the speed of expansion and development of the National Genomic Test Directory.
19. If the question refers to the incorporation of whole genome sequences into patient records, this is a much more challenging proposal, and it would be premature to indicate a timescale for such changes unless or until the contentious issues have been addressed. This would include the nature and format of data storage (raw genome sequences are massive and of highly limited utility without proper processing and interpretation) and the purposes for which such data is being obtained and stored, with all the relevant legal, ethical, regulatory and practical issues this may pose.
20. Technical and practical barriers to the storage and access of data, including stringent measures for future proofing, should be considered. The format of data should be standardised, to national and/or international standards where they exist. Given the size of datasets, and the challenges associated with moving large volumes of data, access via trusted research environments, data trusts or other models will be required to ensure ongoing access and appropriate use of data to improve patient care.

What are the principal considerations that should be taken into account in this context and what additional training of the workforce will be needed to achieve this?

21. There should be no need for non-specialised health professionals to undertake highly specialised interpretation of genomic information, though they may work with colleagues such as clinical geneticists, cancer geneticists, bioinformaticians or others in a multi-disciplinary team context in order to understand (and subsequently communicate) the implications of findings for their own patients. Genomics competencies and training for different specialisms and stages should continue to be determined in partnership with medical Royal Colleges as well as Health Education England.
22. In the context of cancer and rare diseases, there may be an increasing need to include genomic data with relevance to research (for example, suggesting eligibility for clinical trials) as well as immediate clinical care, and this will need careful consideration to ensure there is no confusion or conflation between these two categories of information.

23. If moves towards whole genome sequencing of newborns as part of screening programmes progress, there will be new needs for relevant health professional training in consent, data security and other much wider issues. These will be significant and will require considerable thought to ensure that they are fit for purpose. Until current plans to investigate the desirability and feasibility of such a programme by Genomics England are complete, it would not be appropriate to comment on the timescale or considerations this may pose; however, extensive consultation and co-development with health professionals as well as members of the public will be critical to this process.
24. Genomic information does give rise to particular ethical and legal challenges that training should address, at least in a general sense, to ensure professionals are sensitive to potential concerns. These include the potential importance of results for family members, the potential for unexpected or incidental findings and perhaps more crucially, the inherent uncertainty in many genomic results both for professionals and patients.